

Office Action Summary	Application No. 10/659,100	Applicant(s) SAGEL ET AL.
	Examiner LEZAH ROBERTS	Art Unit 1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,100

09/10/2003

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27752 7590 05/25/2011
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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/25/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed September 24, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 8-10, 19, 20 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leaderman (2002/0061329) in view of McLaughlin (US 6,274,122).

Leaderman discloses system that may be used to deliver whitening agents to teeth. The dressing can be constructed in the form of a sponge or sheet impregnated with the gel, and may contain a tooth-whitener (see Abstract). The backing may be a porous substrate that has air holes and allows the covered area to breath and dry, thus maintaining or increasing the adhesiveness (paragraph 0021). Polymers used in the aqueous gels include vinyl polymers such as polyvinyl pyrrolidone,

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poly(ethylene)oxides, acrylamide polymers and derivatives and salts thereof, encompassing claims 8, 25 and 26. It is also to be understood that poly(ethylene)oxides includes polyethylene glycol (paragraphs 0027 and 0028), encompassing instant claim 9. The gel, foam and/or film formulations in accordance with the preferred embodiments of the invention can be used to coat fibers of an absorbent gauze dressing, nonporous, porous, or micro porous fabric and provide dressings that can be placed in the oral cavity. The gels, foams or film formulations can be applied to the dressing material by soaking, spray coating or dip coating (paragraph 0039). The dressing materials include porous, non-porous, or micro porous polyesters, rayons, cottons, wools, silks, papers, foams (open and closed cell), woven and non-woven fabrics, polyolefins, polyesters, copolyesters, polyurethanes, ethyl vinyl acetate, polyether block amides, ethylene methacrylic acids or polyethylene (paragraph 0041), encompassing claims 10 and 22.

The non-woven and woven fabrics are interpreted as the mesh of the instant claims. The gels are applied by soaking, spray coating or dip coating, which encompasses that the void spaces extends through the thickness of the film and partially fills the mesh. This is also considered as coating the fibers of the fabric.

The reference differs from the instant claims insofar as it does not disclose the size of the recited voids ranges from 1 micrometer to 50 micrometers wide.

McLaughlin discloses devices for whitening teeth. The device comprises an outer and an inner layer. The inner layer is water-permeable and allows penetration of the treatment agent through after an aqueous solution is introduced to the device (Abstract). The inner layer may include holes for facilitating the passage of water. The inner layer

may be a sheet of perforated plastic, open-celled foam or a porous film (col. 4, lines 43-52).

The reference differs from the instant claims insofar as it does not disclose that the devices are films or the size of the void spaces.

The voids facilitate the passage of water to the device and one of ordinary skill in the art would reasonably conclude that the passage of water through the device facilitates the delivery of the active composition based on the disclosure of McLaughlin. Therefore it is reasonable to conclude that the size of the voids is a result effective variable because the voids control the amount and rate of water that penetrates the device. It would have taken no more than the relative skill of one of ordinary skill in the art to have optimized the size of the voids to achieve the desired rate of passage of water to achieve the desired rate of delivery of the active composition. Therefore it would have been obvious to one of ordinary skill in the art to have made the voids of Leaderman from about 1 micrometer to about 50 micrometers wide motivated by the desire to achieve the desired rate of water passage to the device to achieve the desired rate of delivery of the active composition to the teeth.

2) Claims 10, 19, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view of McLaughlin (US 6,274,122).

Jones et al. disclose delivery systems for delivering oral healthcare substances to the teeth. A preferred device is a device comprising a strip with an absorbent material with a peroxide-containing tooth whitening gel. The gel may comprise a gelling agent, which include water hydratable polymers, (paragraph 0035) and carriers such as polyethylene glycol (paragraph 0037) and water (paragraph 0036). The absorbent material includes a fabric, woven or non-woven material. The fabric comprises polypropylene, viscose or a polypropylene-viscose blend (paragraph 0015), encompassing claim 10. The whitening gel may be impregnated into the absorbent's material's bulk. Methods of depositing the oral care materials onto the strips include spraying and dipping. The gel can soak into the adsorbent material and can be completely absorbed by the material, or some may remain unabsorbed as a surface layer. It is found that the absorbent fabric helps to retain the substance on the device (paragraph 0048) The oral care layer may also be in the form of a perforated layer (paragraph 0070).

The non-woven and woven fabrics are interpreted as the mesh of the instant claims. The gels are impregnated or absorbed into the material, which encompasses the void spaces extending through the thickness of the film and partially fills the mesh. This is also considered coating the fibers of the fabric.

The reference differs from the instant claims insofar as it does not disclose the size of the recited voids ranges from 1 micrometer to 50 micrometers wide.

McLaughlin discloses devices for whitening teeth. The device comprises an outer and an inner layer. The inner layer is water-permeable and allows penetration of the

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treatment agent through after an aqueous solution is introduced to the device (Abstract). The inner layer may include holes for facilitating the passage of water. The inner layer may be a sheet of perforated plastic, open-celled foam or a porous film (col. 4, lines 43-52).

The reference differs from the instant claims insofar as it does not disclose that the devices are films or the size of the void spaces.

The voids facilitate the passage of water to the device and one of ordinary skill in the art would reasonably conclude that the passage of water through the device facilitates the delivery of the active composition based on the disclosure of McLaughlin. Therefore it is reasonable to conclude that the size of the voids is a result effective variable because the voids control the amount and rate of water that penetrates the device. It would have taken no more than the relative skill of one of ordinary skill in the art to have optimized the size of the voids to achieve the desired rate of passage of water to achieve the desired rate of delivery of the active composition. Therefore it would have been obvious to one of ordinary skill in the art to have made the voids of Jones et al. from about 1 micrometer to about 50 micrometers wide motivated by the desire to achieve the desired rate of water passage to the device to achieve the desired rate of delivery of the active composition to the teeth.

3) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view of McLaughlin (US 6,274,122) as applied to claims 10, 19, 20 and 22-24 above, in further view of Ruben (US 6,146,655).

Jones et al. in view of McLaughlin is discussed above. The combination of references differs from the instant claim insofar as it does not disclose the diameter of the fibers comprised in the fabric.

Ruben discloses oral bandages and drug delivery systems. The systems are gel/fiber compositions wherein the fiber is used as reinforcement to the gel. The fibers have an individual length of at least 3 mm, and preferably in the range of from about 2 mm to about 4 mm, to obtain the desired reinforcement effect. There should be at least one order of magnitude difference between the diameter and length of the fibers (col. 3, lines 35-45). It is concluded the fibers will have a diameter of at the 200 microns when the length of the fibers is 2 mm. After the kit is removed from the liquid, the tacky fiber-reinforced gel is removed from the package and envelope, and manually molded and positioned in place over a desired tissue surface in a patient's oral cavity. The fiber may be made of natural cellulosic fibers or synthetic fibers (col. 4, lines 53-65).

The reference differs from the instant claim insofar as it does not teach the fibers form a mesh and the compositions include a tooth-whitening agent.

It would have been obvious to one of ordinary skill in the art to have used fabrics with fibers with certain dimensions as the fabrics of the combination of Jones et al in view of McLaughlin motivated by the desire to use material that would reinforce the gel

compositions with the desired reinforcement effect when wet and placed in the mouth as disclosed by the Ruben.

4) Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view McLaughlin (US 6,274,122) as applied to claims 10, 19, 20 and 22-24 above, in further view of Chen et al. (US 6,261,679).

Jones et al. in view of McLaughlin is discussed above. The combination of references differs from the instant claim insofar as it does not disclose the fibers of the fabric comprise a hydratable polymer although it teaches the fibers are coated with a hydratable polymer

Chen et al. disclose hydrophilic fibers are used to make structures with good integrity and resiliency (col. 1, lines 50-55). Fiber enforced foams usually comprise hydrophobic fibers and lack high-bulk, absorbent attributes desired on an absorbent article. The structures of the reference comprise hydrophilic fibers to remedy this problem (col. 1, lines 17-39). The structures may be used as dental absorbents and medical sponges (col. 2, lines 42-60).

The reference differs from the instant claim insofar as it does not disclose the structures comprise oral care agents such as whitening agents.

It would have been obvious to one of ordinary skill in the art to have used hydrophilic fibers as the absorbent fabric for the devices of Jones et al. in view of McLaughlin motivated by the desire to increase the integrity and resiliency of the device

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without subtracting from absorbent attributes desired in an absorbent material, as disclosed by Chen et al.

Claims 7-10 and 19-27 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612